

REMARKS

Upon entry of this amendment, claims 1-3, 6-7, 22-28 and 31-33 are pending in the instant application. Claims 1, 25 and 26 have been amended. Support for the claim amendments presented herein is found throughout the specification and in the claims as originally filed. For example, support for the amendments to claims 1 and 25 is found at least at in Table 1 on pages 11-14 and in the sequence listing as originally filed. Support for the amendment to claim 26 is found at least in paragraph [0058] on pages 16-17. Accordingly, no new matter has been added by the amendments presented herein.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-3, 6-7, 22-28 and 31-33 remain rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. In particular, the Examiner has indicated that “it is apparent that the fully human monoclonal antibody 6.4, 1.9, 1.19, 1.22, and 1.29 produced by hybridoma recited in claims 1 and 25 are required to practice the claimed invention.” (Office Action, page 2).

Applicants respectfully disagree with the Examiner. However, merely to expedite the prosecution, Applicants have amended the claims. In particular, claim 1 has been amended to recite a method of effectively treating nephritis by (i) selecting an animal in need of treatment for nephritis; and (ii) administering to the animal a therapeutically effective dose of a neutralizing antibody, or binding fragment thereof, that binds to platelet derived growth factor-DD (PDGF-DD), wherein the neutralizing antibody, or binding fragment thereof, neutralizes PDGF-DD-induced mitogenic activity, and wherein the neutralizing antibody, or binding fragment thereof, comprises fully human anti-PDGF-DD monoclonal antibody having variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:2 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:4 or an antibody in the same antigen-binding bin as fully human anti-PDGF-DD antibody having a variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:2 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:4, wherein the antibody in the same antigen-binding bin is selected from a fully human antibody having a variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:22 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:24, and a fully human antibody

having a variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:38 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:40, and wherein the nephritis is selected from mesangial proliferative nephritis, mesangial proliferative glomerulonephritis and glomerular nephritis.

Claim 25, as amended, is directed to a method of effectively treating nephritis by (i) selecting an animal in need of treatment for nephritis; and (ii) administering to the animal a therapeutically effective dose of a neutralizing antibody, or binding fragment thereof, that binds to platelet derived growth factor-DD (PDGF-DD), wherein the neutralizing antibody, or binding fragment thereof, neutralizes PDGF-DD-induced mitogenic activity, and wherein the neutralizing antibody, or binding fragment thereof comprises fully human anti-PDGF-DD antibody monoclonal antibody having a variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:2 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:4 or an antibody in the same antigen-binding bin as fully human anti-PDGF-DD antibody having a variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:2 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:4, wherein the antibody in the same antigen-binding bin is selected from a fully human antibody having a variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:22 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:24, and a fully human antibody having a variable region of the heavy chain consisting of the amino acid sequence of SEQ ID NO:38 and a variable region of the light chain consisting of the amino acid sequence of SEQ ID NO:40 and wherein the neutralizing antibody, or binding fragment thereof, comprises a fully human IgG2 heavy chain, and wherein the nephritis is selected from mesangial proliferative nephritis, mesangial proliferative glomerulonephritis and glomerular nephritis.

The amended claims presented herein are enabled by the instant specification. As amended herein, the claims recite the particular amino acid sequences of the heavy and light chain variable regions of the claimed fully human monoclonal antibodies. Applicants submit that the production of fully human monoclonal antibodies having the specific heavy chain and light chain variable region sequences recited by amended claims 1 and 25 is within the ordinary skill of an artisan. Thus, a person of ordinary skill in the art, with the specification in hand and given

the state of the art at the time of filing, could make and use the claimed methods of treating nephritis without undue experimentation.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, for lack of enablement, be withdrawn.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph


Claim 26 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner has stated that the term “further comprises a human kappa light chain” renders the claim ambiguous and indefinite because a fully human antibody “by convention ... comprises a fully human heavy and light chain”. (Office Action, page 3).

Claim 26 has been amended herein to recite that the light chain of the claimed neutralizing antibody is a human kappa light chain. Moreover, the pending claims, as amended herein, do not recite a fully human monoclonal antibody that further comprises a human kappa light chain. Accordingly, Applicants submit that the metes and bounds of this amended claim are clear and definite. As such, withdrawal of this rejection is requested.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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